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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KERR, KATHLEEN M	

ART UNIT	PAPER NUMBER
1652	11

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,384	SHERMAN ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

1. Claims 1-60, as originally filed, are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1. Claims 1-6, 8, 18, 20, and 28, drawn to nucleic acid segments comprising a desosamine biosynthetic gene cluster (pikB), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
2. Claims 1-8, 18, and 28, drawn to nucleic acid segments comprising the DesI fragment of the desosamine biosynthetic gene cluster (SEQ ID NO:7), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
3. Claims 1-8, 18, and 28, drawn to nucleic acid segments comprising the DesII fragment of the desosamine biosynthetic gene cluster (SEQ ID NO:9), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
4. Claims 1-8, 18, and 28, drawn to nucleic acid segments comprising the DesIII fragment of the desosamine biosynthetic gene cluster (SEQ ID NO:11), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
5. Claims 1-8, 18, and 28, drawn to nucleic acid segments comprising the DesIV fragment of the desosamine biosynthetic gene cluster (SEQ ID NO:13), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
6. Claims 1-8, 18, and 28, drawn to nucleic acid segments comprising the DesV fragment of the desosamine biosynthetic gene cluster (SEQ ID NO:15), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
7. Claims 1-8, 18, and 28, drawn to nucleic acid segments comprising the DesVI fragment of the desosamine biosynthetic gene cluster (SEQ ID NO:17), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
8. Claims 1-8, 18, and 28, drawn to nucleic acid segments comprising the DesVII fragment of the desosamine biosynthetic gene cluster (SEQ ID NO:19), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.

9. Claims 1-8, 18, and 28, drawn to nucleic acid segments comprising the DesVIII fragment of the desosamine biosynthetic gene cluster (SEQ ID NO:21), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
10. Claims 1-8, 18, 28, 57, and 59, drawn to nucleic acid segments comprising the DesR fragment of the desosamine biosynthetic gene cluster (SEQ ID NO:23), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
11. Claims 9-11, 21-22, 46, 55, 58, and 60, polyketides, classified in class 568, subclass 382.
12. Claims 12-14, 16-18, and 28, drawn to nucleic acid segments comprising a macrolide (methymycin, pikromycin, neomethymycin, narbomycin) biosynthetic gene cluster, vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
13. Claims 12-18, 20, and 28 drawn to nucleic acid segments comprising the PikR1 fragment of the macrolide biosynthetic gene cluster (SEQ ID NO:26), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
14. Claims 12-18, 20, and 28 drawn to nucleic acid segments comprising the PikR2 fragment of the macrolide biosynthetic gene cluster (SEQ ID NO:28), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
15. Claims 12-18, 20, 23, 25, and 28, drawn to nucleic acid segments comprising the PikAI fragment of the macrolide biosynthetic gene cluster (SEQ ID NO:30), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
16. Claims 12-18, 20, 23, 25, and 28, drawn to nucleic acid segments comprising the PikAII fragment of the macrolide biosynthetic gene cluster (SEQ ID NO:32), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
17. Claims 12-18, 20, 23, 25, and 28, drawn to nucleic acid segments comprising the PikAIII fragment of the macrolide biosynthetic gene cluster (SEQ ID NO:34), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
18. Claims 12-18, 20, 23, 25, and 28-30, drawn to nucleic acid segments comprising the PikAIV fragment of the macrolide biosynthetic gene cluster (SEQ ID NO:36), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
19. Claims 12-18, 20, 23, and 28, drawn to nucleic acid segments comprising the PikAV fragment of the macrolide biosynthetic gene cluster (SEQ ID NO:?), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.

20. Claims 12-18, 20, and 28, drawn to nucleic acid segments comprising the PikC fragment of the macrolide biosynthetic gene cluster (SEQ ID NO:38), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
21. Claims 12-18, and 28, drawn to nucleic acid segments comprising the PikD fragment of the macrolide biosynthetic gene cluster (SEQ ID NO:40), vectors, and host cells thereof wherein the cluster is either augmented or deleted, classified in class 435, subclass 252.3.
22. Claim 19, drawn to DesI polypeptides encoded by SEQ ID NO:7 or related sequences, classified in class 435, subclass 232.
23. Claim 19, drawn to DesII polypeptides encoded by SEQ ID NO:9 or related sequences, classified in class 435, subclass 190.
24. Claim 19, drawn to DesIII polypeptides encoded by SEQ ID NO:11 or related sequences, classified in class 435, subclass 193.
25. Claim 19, drawn to DesIV polypeptides encoded by SEQ ID NO:13 or related sequences, classified in class 435, subclass 232.
26. Claim 19, drawn to DesV polypeptides encoded by SEQ ID NO:15 or related sequences, classified in class 435, subclass 193.
27. Claim 19, drawn to DesVI polypeptides encoded by SEQ ID NO:17 or related sequences, classified in class 435, subclass 193.
28. Claim 19, drawn to DesVII polypeptides encoded by SEQ ID NO:19 or related sequences, classified in class 435, subclass 193.
29. Claim 19, drawn to DesVIII polypeptides encoded by SEQ ID NO:21 or related sequences, classified in class 435, subclass 233.
30. Claim 19, drawn to DesR polypeptides encoded by SEQ ID NO:23 or related sequences, classified in class 435, subclass 200.
31. Claim 19, drawn to PikR1 polypeptides encoded by SEQ ID NO:26 or related sequences, classified in class 435, subclass 193.
32. Claim 19, drawn to PikR2 polypeptides encoded by SEQ ID NO:28 or related sequences, classified in class 435, subclass 193.
33. Claim 19, drawn to PikAI polypeptides encoded by SEQ ID NO:30 or related sequences, classified in class 435, subclass 183.
34. Claim 19, drawn to PikAII polypeptides encoded by SEQ ID NO:32 or related sequences, classified in class 435, subclass 183.
35. Claim 19, drawn to PikAIII polypeptides encoded by SEQ ID NO:34 or related sequences, classified in class 435, subclass 183.
36. Claim 19, drawn to PikAIV polypeptides encoded by SEQ ID NO:36 or related sequences, classified in class 435, subclass 183.
37. Claim 19, drawn to PikAV polypeptides encoded by SEQ ID NO:? or related sequences, classified in class 435, subclass 196.
38. Claim 19, drawn to PikC polypeptides encoded by SEQ ID NO:38 or related sequences, classified in class 435, subclass 190.
39. Claim 19, drawn to PikD polypeptides encoded by SEQ ID NO:40 or related sequences, classified in class 530, subclass 350.

40. Claims 24, 26, and 27, drawn to methods of making a polyhydroxyalkanoate (PHA) monomer using a PikAI DNA segment, classified in class 435, subclass 158.
41. Claims 24, 26, and 27, drawn to methods of making a polyhydroxyalkanoate (PHA) monomer using a PikAII DNA segment, classified in class 435, subclass 158.
42. Claims 24, 26, and 27, drawn to methods of making a polyhydroxyalkanoate (PHA) monomer using a PikAIII DNA segment, classified in class 435, subclass 158.
43. Claims 24, 26, and 27, drawn to methods of making a polyhydroxyalkanoate (PHA) monomer using a PikAIV DNA segment, classified in class 435, subclass 158.
44. Claims 24, 26, and 27, drawn to methods of making a polyhydroxyalkanoate (PHA) monomer using a PikAV DNA segment, classified in class 435, subclass 158.
45. Claims 31-41, drawn to DNA molecules and vectors containing a pikA promoter, classified in class 536, subclass 24.1.
46. Claims 42-45, drawn to methods of altering polyketide chain length by inserting a TE domain, classified in class 435, subclass 76.
47. Claims 47-50, drawn to methods of making a polyketide, classified in class 435, subclass 76.
48. Claims 51-54, drawn to host cells, classified in class 435, subclass 252.3.
49. Claim 56, drawn to methods of using polyketides, classified in class 514, subclass 183.

3. The inventions are distinct, each from the other because of the following reasons:

The products of Group 1 and the products of Groups 2-10 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the DesR gene encoding a glucosidase involved in a resistance mechanism can be replaced from within the entire cluster of Group 1 with a gene encoding a protein of the same function. The subcombination has separate utility such as converting particular substrates, such as DesV transaminating a substrate to produce a

product that is not a desosamine. Thus, Group 1 is patentably distinct from Groups 2-10. Because these inventions are distinct for the reasons given above and the search required for Group 1 (the entire cluster) is not required for Groups 2-10 (particular fragments) since if any portion of the entire cluster is free of the prior art, the entire cluster is free of the prior art even if a particular fragment is known in the art, restriction for examination purposes as indicated is proper.

Groups 1-10 are related to the polyketide of Group 11 because the DNA encodes proteins that can synthesize the polyketides. However, the nucleic acids and the polyketides are wholly different products having wholly different structures and functions. Thus, Groups 1-10 are patentably distinct from Group 11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group 1 (Des cluster) and Groups 2-10 are related to Groups 12-21 (Pik cluster and fragments) because both clusters encode enzymes that produce polyketides. However, these clusters are distinct from each other based on wholly different structures that support wholly distinct functions. The fragments of the cluster are distinct for the same reasons. Thus, Group 1 is patentably distinct from Groups 12-21. Because these inventions are distinct for the reasons given above and the search required for Groups 1-10 (Des cluster, SEQ ID NO:3,and fragments) is not required for Groups 12-21 (Pik cluster, SEQ ID NO:5, and fragments) since both the sequence searches and text searches are not co-extensive, restriction for examination purposes as indicated is proper.

The DNA of Groups 1-10 is related to the enzymes of Groups 22-30 by virtue of the fact that the DNA encode the enzymes. The DNA molecule has utility for the recombinant production of the enzyme in a host cell. Although the DNA and the enzyme are related, they are distinct inventions because they are wholly different in structure and function. Moreover, the enzyme product can be made by other and materially distinct processes, such as purification from a natural source; and the DNA product can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, Groups 1-10 are patentably distinct from Groups 22-30. Because these inventions are distinct for the reasons given above and the search required for Groups 1-10 is not required for Groups 22-30, restriction for examination purposes as indicated is proper. For example, claims in Group 22, drawn to polypeptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the nucleic acid sequences must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups 1-10 and 22-30 have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

The DNA of Groups 1-10 are related to the polypeptides of Groups 31-39 because the DNA encodes polyketide synthase (PKS) polypeptides and the polypeptides are PKS polypeptides. However, the DNA do not encode these PKS polypeptides of Groups 31-39 and their structures and functions are wholly distinct. Thus, Groups 1-10 are patentably distinct from Groups 31-39. Because these inventions are distinct for the reasons given above and have

acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of Groups 1-10, 12-14, and 20-21 are related to the methods of Groups 40-44 because said methods use PKS DNA. However, these methods do not use the DNA of any of Groups 1-10, 12-14, and 20-21. Nor do these methods make the DNA of any of Groups 1-10, 12-14, and 20-21. Thus, Groups 1-10, 12-14, and 20-21 are patentably distinct from Groups 40-44. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of Groups 1-10 and 12-21 are related to the DNA of Group 45 because the DNA of Groups 1-10 and 12-21 encode PKSs and the DNA of Group 45 is a promoter of a PKS gene. However, these DNAs are structurally and functionally distinct. Thus, Groups 1-10 and 12-21 are patentably distinct from Group 45. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of Groups 1-10 and 12-21 is related to the methods of Groups 46 and 47 because the methods use PKS genes, though not specific to the DNA of Groups 1-10 and 12-21. Thus, the DNA is neither made nor used in the methods. Thus, Groups 1-10 and 12-21 are patentably distinct from Groups 46 and 47. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of Groups 1-10 and 12-21 is related to the host cells of Group 48 because the host cells contain PKS genes, though not specific to the DNA of Groups 1-10 and 12-21. Thus, the DNA is not a necessary part of the host cells of Group 48. Thus, Groups 1-10 and 12-21 are patentably distinct from Group 48. Because these inventions are distinct for the reasons given above and the search required for Groups 1-10 and 12-21 is not required for Group 48, restriction for examination purposes as indicated is proper.

The DNA of Groups 1-10 and 12-21 is related to the methods of Group 49 because the methods use polyketides which can be produced by PKS genes, though not specific to the DNA of Groups 1-10 and 12-21. Thus, the DNA is neither made nor used in the methods. Thus, Groups 1-10 and 12-21 are patentably distinct from Group 49. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polyketides of Group 11 are related PKS genes of Groups 12-21 because the DNA encodes proteins that can synthesize the polyketides. However, the nucleic acids and the polyketides are wholly different products having wholly different structures and functions. Thus, Group 11 is patentably distinct from Groups 12-21. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polyketides of Group 11 are related to the proteins of Groups 22-39 because proteins that can synthesize the polyketides. However, the proteins and the polyketides are wholly different products having wholly different structures and functions. Thus, Group 11 is patentably distinct from Groups 22-39. Because these inventions are distinct for the reasons

given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group 11 is related to Groups 40-44 as polyketides are related to PHA. However, the methods of Groups 40-44 do not make or use the polyketides of Group 11. Thus, Group 11 is patentably distinct from Groups 40-44. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polyketides of Group 11 are related PKS promoter of Group 45 because the DNA promotes DNA that encodes proteins that can synthesize the polyketides. However, the nucleic acids and the polyketides are wholly different products having wholly different structures and functions. Thus, Group 11 is patentably distinct from Group 45. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polyketides of Group 11 is related to the methods of Groups 46 and 47 because the methods use PKS genes to make polyketides, though not specific to the polyketides of Group 11. Thus, the polyketides are neither made nor used in the methods. Thus, Group 11 is patentably distinct from Groups 46 and 47. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polyketides of Group 11 are related to the host cells of Group 48 because the host cells contain PKS genes that produce polyketides, though not specific to the polyketides of Group 11. Thus, the polyketides are not a necessary part of the host cells of Group 48. Thus,

Group 11 is patentably distinct from Group 48. Because these inventions are distinct for the reasons given above and the search required for Group 11 is not required for Group 48, restriction for examination purposes as indicated is proper.

Groups 11 and 49 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the polyketide can be used for a materially different process of using the product, such as in organic synthesis as complex, starting compounds. Thus, Group 11 is patentably distinct from Group 49. Because these inventions are distinct for the reasons given above and the search required for Group 11 is not required for Group 48, restriction for examination purposes as indicated is proper.

The DNA of Groups 12-21 are related to the polypeptides of Groups 22-30 because the DNA encodes polyketide synthase (PKS) polypeptides and the polypeptides are PKS polypeptides. However, the DNA do not encode these PKS polypeptides of Groups 22-30 and their structures and functions are wholly distinct. Thus, Groups 12-21 are patentably distinct from Groups 22-30. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of Groups 12-21 is related to the enzymes of Groups 31-39 by virtue of the fact that the DNA encode the enzymes. The DNA molecule has utility for the recombinant production of the enzyme in a host cell. Although the DNA and the enzyme are related, they are

distinct inventions because they are wholly different in structure and function. Moreover, the enzyme product can be made by other and materially distinct processes, such as purification from a natural source; and the DNA product can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, Groups 12-21 are patentably distinct from Groups 31-39. Because these inventions are distinct for the reasons given above and the search required for Groups 12-21 is not required for Groups 31-39, restriction for examination purposes as indicated is proper. For example, claims in Group 31, drawn to polypeptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the nucleic acid sequences must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups 12-21 and 31-39 have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

The DNAs of Groups 15-19 are related to the methods of Groups 40-44, respectively, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the DNAs can be used for a materially different process of using the product, such as in hybridization assays for the identification of related genes in other species. Thus, Groups 15-19 are patentably distinct from Groups 40-44. Because these inventions are distinct for the reasons given above and have

acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polypeptides of Groups 22-39 are related to the methods of Groups 40-44 because some of the polypeptides are encoded by the DNA used in the methods. However, the proteins are not used in the methods absent the DNA, thus, the methods are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polypeptides of Groups 22-39 are related to the DNA of Group 45 because the DNA is a promoter of PKS genes and the polypeptides are encoded by PKS genes. However, the structures and functions of Groups 22-39 are wholly distinct from that of Group 45. Thus, Groups 22-39 are patentably distinct from Group 45. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polypeptides of Groups 22-39 are related to the methods of Groups 46-47 because said methods use PKS genes. However, the polypeptides themselves are neither made nor used in the methods. Thus, Groups 22-39 are patentably distinct from Groups 46-47. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polypeptides of Groups 22-39 are related to the host cells of Group 48 because the host cells produce PKSs; however, not the PKS proteins in Groups 22-39 specifically. Thus,

Groups 22-39 are patentably distinct from Group 48. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polypeptides of Groups 22-39 are neither used nor made in the methods of Claim 49 although the polypeptides can be used to produce the polyketides used in the methods. Thus, Groups 22-39 are patentably distinct from Group 49. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Groups 40-44 are related to Group 45 as methods that use PKS genes and a promoter of PKS genes. However, the methods do not specifically use the promoter of Group 45. Thus, Groups 40-44 are patentably distinct from Group 45. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups 40-44 are related to the methods of Groups 46-47 because said all the methods use PKS genes. However, the methods all use distinct PKS genes to produce distinct products using distinct method steps. Thus, Groups 40-44 are patentably distinct from Groups 46-47. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups 40-44 are related to the host cells of Group 48 because the host cells produce PKSs; however, not the PKS proteins used in the methods of Groups 40-44 specifically. Thus, Groups 40-44 are patentably distinct from Group 48. Because these

inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups 40-44 are drawn to wholly distinct method steps with respect to the methods of Claim 49 although the polypeptides of all of the methods can be used to produce the polyketides used in the methods. Thus, Groups 40-44 are patentably distinct from Group 49. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNAs of Group 45 are related to the methods of Groups 46-47 because said the methods use PKS genes and the DNAs promoter PKS gene expression. However, the methods use distinct PKS genes to produce distinct products using distinct method steps with respect to the DNA of Group 45. Thus, Group 45 is patentably distinct from Groups 46-47. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of Group 45 is related to the host cells of Group 48 because the host cells produce PKSs and the DNAs promoter PKS gene expression; however, not the PKS proteins promoted by the DNA of Group 45 specifically. Thus, Group 45 is patentably distinct from Group 48. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The DNA of Group 45 is drawn to wholly distinct method steps with respect to the methods of Claim 49 although the DNA of all of the methods can be used to produce the polyketides used in the methods. Thus, Group 45 is patentably distinct from Group 49. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups 46, 47, and 49 are all related to polyketides and the expression of their encoding genes. However, each of these Groups use distinct method steps to produce distinct products using distinct reagents. Thus, Groups 46, 47, and 47 are all patentably distinct from each other. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups 46, 47 , and 49 are all related to the host cells of Group 48 because all are related to polyketide synthases. However, the host cells are neither used nor made in any of the methods, specifically. Thus, Groups 46, 47, and 49 are patentably distinct from Group 48. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

4. The Examiner notes that if product claims in Group 11 are found directed to an allowable product, then process claims in Group 49, which are directed to processes of using the patentable

product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Additionally, product Groups 15-19 are related to method Groups 40-44 as noted above and would be available for rejoinder upon identification of allowable subject matter.

Election

5. A telephone call was made to Janet Embertson on September 29, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

6. A complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
September 29, 2003